IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: *Konrad v. AbbVie Inc.*, No. 1:15-cv-00966	

PLAINTIFF'S RESPONSE IN OPPOSITION TO ABBVIE'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR ALTERNATIVELY FOR A NEW TRIAL OR REMITTITUR

December 1, 2017

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Rules

Other Authorities

INTRODUCTION

After a thirteen-day trial over two and a half weeks, the jury in this case deliberated extensively and returned a unanimous verdict in favor of Plaintiff Jeffrey Konrad as to his claims of negligence, intentional misrepresentation, and misrepresentation by concealment, awarding $140,000.00 in compensatory damages ($100,000.00 for pain and suffering and $40,000.00 for medical expenses) and $140,000,000.00 in punitive damages. *See* Judgment (*Konrad* Dkt. No. 112); Verdict Form (*Konrad* Dkt. No. 114). Defendants AbbVie Inc. and Abbott Laboratories (collectively, "AbbVie") now request judgment as a matter of law, or in the alternative a new trial or remittitur, taking a scattershot approach and requesting a panoply of post-trial remedies that should all be rejected (the "Motion" or "AbbVie Mot.", MDL Dkt. No. 2231, *Konrad* Dkt. No. 118). AbbVie argues, *inter alia*, that Plaintiff's evidence was insufficient, that the verdict was inconsistent, and that the punitive damages award was excessive. However, AbbVie's Motion repeatedly mischaracterizes the record evidence and misconstrues the applicable law. The judgment entered in accordance with the jury's verdict should stand, and the Court should deny the Motion in its entirety.

BACKGROUND

Over the course of this trial, the jury heard testimony from world renowned scientists and physicians with expertise in pharmacology, cardiology, drug development and testing, drug safety, labeling, and the FDA, as well as from AbbVie's own employees, regarding AbbVie's misrepresentations and omissions concerning AndroGel, its failure to demonstrate AndroGel's safety and efficacy for the uses it promoted, and the serious cardiovascular ("CV") risks the drug presented. As a result, the jury heard that Mr. Konrad was exposed to a drug without benefit—but one that did carry substantial undisclosed risk—and thereafter suffered a heart attack.

Through AbbVie's documents and the testimony of company witnesses, Mr. Konrad demonstrated that, despite seeking and obtaining approval of AndroGel for the treatment of specific conditions with a limited prevalence in the general population, from the inception AbbVie sought to market and promote AndroGel to a much wider audience for uses that it had never proven

the drug to be safe or effective in treating. *See, e.g.*, Ex. 1 (Trial Ex. 1) (Grow the Market, Grow your Bonus); Ex. 2 (Trial Ex. 9.33).[1] AbbVie's stark objective in doing so was to increase its sales of AndroGel well beyond anything that could be achieved within the limited market of patients for which the drug had been approved. The evidence at trial demonstrated that AbbVie's unabashed marketing of AndroGel for untested and unproven uses worked. By 2010, the year that Mr. Konrad was prescribed AndroGel, AbbVie's sales of AndroGel were fifteen-fold greater than the combined sales of all testosterone replacement products ("TRT") in the mature market that existed at the time AndroGel was launched. *See* Ex. 3 (Trial Ex. 52.287).

As the examination of AbbVie employees Steven Wojtanowski and James Hynd revealed, AbbVie was on notice by 2000 that: (1) there was no evidence that AndroGel was safe or effective for "age-related hypogonadism" or symptoms of aging, such as fatigue, erectile dysfunction, low libido, mood, muscle strength, or body composition; (2) AndroGel was never indicated for those uses; and (3) "claims and representations that *suggest* AndroGel is indicated for men with 'age-associated' hypogonadism or andropause' are *misleading*." Trial Transcript ("Tr.") at 299:10-300:22 (emphases added) (Tr. excerpts attached hereto as Ex. 4); see also Tr. 323:11-325:8, 325:15-327:2, 341:15-342:2, 945:20-946:2, 288:23-289:11.

Notwithstanding such limitations and concerns, AbbVie marketed and promoted TRT and AndroGel for the symptoms of aging. *See, e.g.,* Tr. 945:17-19, 945:24-946:7, 289:9-11, 329:21-330:10 (AbbVie claimed significant symptom improvement over time, even though AndroGel had never been indicated for the treatment of erectile dysfunction, fatigue, or depression). In doing so, AbbVie's promotional materials and advertisements touted information about benefits and made reassurances of safety. *See, e.g.,* Ex. 5 (Trial Ex. 630) (touting benefits of treating a condition referred to as "Low T" and symptom relief); Ex. 6 (Trial Ex. 81.8) (AndroGel "proven safe" for 42 months of use); Ex. 7 (Trial Ex.154.5) ("AndroGel restores T levels and provides significant

[1] Due to ECF size restrictions, copies of exhibits attached hereto will be filed separately with the Clerk of Court by compact disk. Defendants' liaison counsel will receive electronic copies of these exhibits and a courtesy copy will be delivered to the Court.

symptom improvement over time"); Ex. 8 (Trial Ex. 2000.5) ("I just didn't have the same energy. When my doctor told me I had Low T, I started using AndroGel…Now I have more energy"); Ex. 9 (Trial Ex. 585.7) ("[u]se daily for continued *symptom relief*") (emphasis added).

Dr. David Kessler affirmed that contrary to the Company's claims, and as the FDA repeatedly advised, AbbVie's clinical testing did not demonstrate the safety and efficacy of AndroGel for the treatment of the symptoms of aging. Additionally, before AbbVie could market AndroGel for the symptoms of aging, further testing would be necessary to demonstrate the safety and efficacy of the drug for those uses. *See* Tr. 341:15-343:3; Ex. 10 (Trial Ex. 23.8) (stating AbbVie needed to demonstrate AndroGel's long-term safety, including for cardiac health); Ex.11 (Trial Ex. 25.6); Ex. 12 (Trial Ex. 238.1-2); *see also* Ex. 13 (Trial Ex. 26.17). Prior to Mr. Konrad's use of AndroGel, the FDA repeatedly echoed those concerns. *See* Tr. 945:4-13; Ex. 12 (Trial Ex. 238.1); Tr. 753:1-10.

Indeed, the call for caution—which went unheeded in AbbVie's promotion of the drug—was well founded. As Dr. Ardehali testified, TRT and AndroGel increase the risk, and are a cause, of severe cardiovascular hazards, including heart attacks. *See* Tr. 1301:10-13; 1440:5-21. Dr. Ardehali detailed the evidence supporting that conclusion, which included numerous non-clinical and mechanistic studies, population and epidemiological studies, and clinical studies (and associated meta-analyses of such data). Tr. 1335:1-1379:3, 1388:8-1440:21. He further confirmed, based on a review of available studies and internal AbbVie reports, that there was reasonable evidence of a causal association with AndroGel and heart attacks by 2007. Tr. 1302:6-8. In the face of such information, as industry expert Dr. Peggy Pence testified, a reasonable pharmaceutical company would have changed its label to reflect the serious risks of the drug, and taken measures to test and limit use to the indications in which there was safety and efficacy. Tr. 2409:21-2411:17.

Such testing, limitations, and warnings were notably absent in 2010, when Mr. Konrad was exposed to AbbVie's promotion and associated claims of testosterone treatment benefits for the symptoms of aging. Tr. 1586:16-1587:14. Thus, when feeling fatigued in the spring of 2010, Mr. Konrad made an appointment to see Dr. Steven Overby for that and other symptoms AbbVie

claimed testosterone treated—and he asked his doctor. Tr. 1586:21-1587:22. Then, consistent with the messaging Dr. Overby had been exposed to in the more than 120 detail visits by AbbVie's cadre of sales representatives, Dr. Overby tested Mr. Konrad's testosterone level. Based on Mr. Konrad's "low testosterone" level and presenting symptoms of fatigue and low libido, Dr. Overby thereafter prescribed AndroGel for Mr. Konrad. Tr. 1587:25-1588:1; 1588:15-16, 1613:10-18. Two short months later, Mr. Konrad suffered a heart attack. Against the backdrop of a clean stress test and informed by the data and studies demonstrating testosterone's immediate effect on the blood and clotting activity—and its associated heart attack risk—Dr. Phillip Cuculich testified that AndroGel was a cause of Mr. Konrad's heart attack. Tr. 1668:24-1669:3, 1806:13-25, 1649:23-1650:8, 1739:13-20.

The net result is that the jury in this case, based on substantial and credible evidence, found for Mr. Konrad on three separate counts and awarded him damages. Nothing in AbbVie's Motion permits the relief it requests.

LEGAL STANDARD

In considering a motion for judgment as a matter of law under Fed. R. Civ. P. 50, a trial court is required to draw all inferences in favor of the nonmoving party and to disregard all evidence favoring the moving party that the jury was not required to believe. *See Tart v. Illinois Power Co.*, 366 F.3d 461, 472 (7th Cir. 2004). In order to overturn a verdict in one party's favor, "there must have been no legally sufficient evidentiary basis for a reasonable jury to find for the non-moving party." *Sheehan v. Donlen Corp.*, 173 F.3d 1039, 1043 (7th Cir. 1999).

"[V]erdicts are to be interpreted to avoid inconsistency" and "jurors are presumed to have followed their instructions." *See Jamsports and Entm't, LLC v. Paradama Prods., Inc.*, 382 F. Supp. 2d 1056, 1060 (N.D. Ill. 2005). "If it appears that the jury returned inconsistent verdicts, the Court must first do its best to reconcile the verdicts on some theory consistent with the evidence." *Golden v. World Sec. Bureau, Inc.*, 988 F. Supp. 2d 850, 854 (N.D. Ill. 2013) (internal quotation marks omitted) (citing *Deloughery v. City of Chicago*, 2004 WL 1125897, at *2 (N.D. Ill. May 20, 2004), *aff'd*, 422 F.3d 611 (7th Cir.2005)).

To prevail on a motion under Fed. R. Civ. P. 59(e), the movant must either show a "manifest error of law or fact" or "present newly discovered evidence." *Boyd v. Tornier, Inc.*, 656 F.3d 487, 492 (7th Cir. 2011). "A 'manifest error' is not demonstrated by the disappointment of the losing party. It is the 'wholesale disregard, misapplication, or failure to recognize controlling precedent'." *Oto v. Metro. Life Ins. Co.*, 224 F.3d 601, 606 (7th Cir. 2000) (quoting *Sedrak v. Callahan*, 987 F. Supp. 1063, 1069 (N.D. Ill. 1997)).

ARGUMENT

I. THE COURT SHOULD DENY ABBVIE'S MOTION FOR JUDGMENT AS A MATTER OF LAW BECAUSE PLAINTIFF PRESENTED SUBSTANTIAL EVIDENCE TO SUPPORT THE JURY'S FINDINGS OF LIABILITY AND DAMAGES

A. There Was Sufficient Evidence to Establish That AndroGel Was a Cause In Fact of Plaintiff's Myocardial Infarction (MI)

AbbVie claims that Plaintiff failed to produce evidence that AndroGel was a but-for, or "cause in fact," of Plaintiff's MI. By so arguing, AbbVie misconstrues Tennessee law and the opinion testimony of Plaintiff's experts, Drs. Cuculich and Ardehali. AbbVie's conduct was a cause in fact of Mr. Konrad's injury if, as a factual matter, it directly contributed to his injury. *Hale v. Ostrow*, 166 S.W.3d 713, 718 (Tenn. 2005); T.P.I.-Civil 3.21 Cause in Fact.

1. Dr. Cuculich's Testimony Established That AndroGel Was A Cause In Fact Of Plaintiff's MI

Dr. Cuculich testified at length in support of his opinion that AndroGel caused Plaintiff's heart attack. *See, e.g.*, Tr. 1649:23-1650:3, 1667:11-1668:2, 1707:10-20, 1711:21-1712:7, 1714:23-1715:8, 1733:23-1734:2, 1739:13-20. In Dr. Cuculich's opinion, prior to his heart attack, Plaintiff had underlying small plaque in his left anterior descending artery (LAD) resulting in a 10-20% stenosis. Tr. 1714:23-1715:8. The small plaque ruptured, and then AndroGel caused a vigorous response to the rupture, which in turn was the immediate cause of the development of a large clot on top of his pre-existing small plaque. 1707:13-16, 1734:20-1735:12, 1739:13-20. This large clot blocked blood flow in the LAD, which directly led to Plaintiff's heart attack. Tr. 1667:15-17, 1670:19-24.

Dr. Cuculich also ruled out other potential causes besides AndroGel as the immediate cause of Plaintiff's heart attack. For instance, Dr. Cuculich relied upon the normal stress test that was

performed less than two weeks before Mr. Konrad's heart attack and the results of the heart catheterization performed shortly after Plaintiff's MI, which showed no lesions in the other main arteries, in support of his view that the 75% stenosis in the LAD found at the time of the heart catheterization was not the result of underlying coronary artery disease. Tr. 1703:1-5, 1703:24-1704:12, 1706:23-1707:9. *See also* Tr. 1717:17-1718:24, 1723:25-1724:5, 1724:1-11, 1724:14-15, 1730:11-13 (ruling out other medical conditions and age); Tr. 1732:15-1733:19 (ruling out other potential causes of large clot). Dr. Cuculich's testimony along with the evidence upon which he relied provided a sufficient basis for the jury to conclude that Plaintiff's MI would not have otherwise occurred but for his use of AndroGel. *See Dickson v. Kriger,* 2014 WL 7427235, at *3, 6 (Tenn. Ct. App. Dec. 30, 2014) (finding sufficient evidence of causation even in absence of expert testifying that plaintiff's injuries "would not have otherwise occurred but for the alleged medical negligence"). Nor does the cramped reading of Dr. Cuculich's testimony advocated by AbbVie – even were it to stand alone – reveal an absence of evidence that AndroGel was a cause in fact of Plaintiff's MI.[2] Under Tennessee law, "the 'substantial factor' test, like the 'but for' test, incorporates the concept that conduct cannot be a cause in fact of an injury if the injury would still have occurred even if the conduct had never taken place." *Waste Mgmt. v. South Cent. Bell Tel. Co.*, 15 S.W.3d 425, 432 (Tenn. Ct. App. 1997); *see also Lancaster v. Montesi,* 390 S.W.2d 217, 220 (Tenn. 1965).

2. The Evidence Established Plaintiff's AndroGel Use Over Time And On The Date Of His MI

Mr. Konrad received his first AndroGel 1% prescription on May 5, 2010 at a dosage of 5g per day, and refilled his prescription on June 24, 2010. Ex. 14 (Trial Ex. 2126.66). Mr. Konrad

[2] Ignoring Dr. Cuculich's broader testimony concerning AndroGel's role in Mr. Konrad's heart attack, AbbVie suggests that his testimony regarding "substantial factor" only "goes to proximate, not but-for, causation." AbbVie Mot. at 3. However, a reasonable reading of Dr. Cuculich's testimony demonstrates his opinion was that AndroGel was a substantial factor and directly contributed to Plaintiff's heart attack. Tr. 1649:23-1650:3, 1663:18-22, 1667:7-10. When construing the contents of a medical expert's testimony—and likewise in interpreting what reasonable inferences a jury may draw therefrom—the Court should review the testimony "as the testimony of a medical person and not that of any individual trained in the law." *Miller v. Choo Choo Ptnrs., LP,* 73 S.W.3d 897, 905 (Tenn. Ct. App. 2001) ("We are expecting too much if we think doctors can speak with the precision of a hornbook on causation.").

testified unequivocally that he used AndroGel daily, as prescribed, until the time of his heart attack on July 9, 2010. Tr. 1627:17-19. The hospital record confirmed that Mr. Konrad remained on AndroGel at the time of admission for treatment of his MI. Ex. 14 (Trial Ex. 2126.66). Thus, a reasonable inference from the medical and pharmacy records is that Mr. Konrad was a current user of AndroGel on the day of his heart attack, and that he had used it daily prior to his event. Addressing AbbVie's exposure challenge at trial, Dr. Ardehali explained that published data from the AbbVie's clinical study of its AndroGel 1.62% product showed that patients receiving 1.25g of AndroGel – an exposure substantially less than the amount of testosterone used by plaintiff – experienced immediate elevations of their testosterone levels (to greater than 300 ng/dL). Tr. 1436:19-1439:13. Similarly, the same clinical trial reported striking increases in the estradiol levels for these patients during the first 30 days of treatment – a finding consistent with short-term risk through this mechanistic pathway. Tr. 1440:11-15. Indeed, as Dr. Ardehali testified, dosages of AndroGel lower than the dosage that AbbVie contends Plaintiff received can increase the risk of heart attacks in short terms users. Tr. 1440:5-21.

Despite its complaints, AbbVie cannot avoid the trial evidence that Mr. Konrad was using AndroGel on the day of his event, and that its marketing materials repeatedly touted AndroGel's ability to raise testosterone levels within the first day of use. *See, e.g.*, Tr. 330:25-331:4, 331:13-19; Ex. 7 (Trial Ex. 154.4); Ex. 6 (Trial Ex. 81.6); Ex. 8 (Trial Ex. 2000.5). Dr. Cuculich further testified, without objection, that, based on his review of the prescription records, in combination with his review of the medical literature, Mr. Konrad received a sufficient amount of AndroGel to have caused his MI, providing a sound basis for the jury's determination. Tr. 1734:3-1737:17. In the end, the trial evidence established that Plaintiff was on AndroGel and fully exposed its effects as of the day of his MI, and that his use of AndroGel was the cause in fact of his MI.

3. AbbVie Mischaracterizes Testimony on Scientific Evidence

AbbVie argues that none of the epidemiology studies relied upon by Dr. Ardehali fit Mr. Konrad's age and usage profile. *See* AbbVie Mot. at 3. Though this argument plainly goes to the weight of the evidence, it is even then premised on a flawed and selective review of the "evidence."

Indeed, Plaintiff's experts provided ample reasoning for their reliance on the extant epidemiology to find causation in this case. Tr. 1417:13-14, 1418:16-19, 1421:1-10, 1421:25-1422:9, 1422:25-1423:8, 1542:25-1543:3, 1543:23-1544:4.

B. Plaintiff Presented Substantial Evidence that AbbVie Failed to Properly Warn and that Proper Warnings Would Have Prevented Mr. Konrad's MI

1. AbbVie Failed to Properly Warn

Plaintiff presented substantial evidence that AbbVie failed to properly warn Dr. Overby, and relatedly Mr. Konrad, of the increased risk of heart attack. Indeed, as detailed, *infra* at 10, a proper warning would have prevented Mr. Konrad's heart attack.

The record is replete with evidence that AbbVie failed to adequately warn, in the label or otherwise, of the increased risks of CV events with AndroGel use until required to do so by FDA in 2015. *See, e.g.*, Ex. 15 (Trial Ex. 60.6) ("Major Safety Concerns: Cardiovascular Disease"). The jury learned that these risks were well-documented internally at AbbVie for years prior to Mr. Konrad's heart attack. In addition to other information indicating the cardiovascular risks posed by AndroGel, AbbVie was also aware of pre- and post-marketing cardiovascular events contained within its pharmacovigilance database. *See also* Tr. 2390:8-22; 2395:13-2397:3; 2405:3-9; Ex. 16 (Trial Ex. 807a); Ex. 17 (Trial Ex. 420); Ex. 18 (Trial Ex. 807d); Ex. 19 (Trial Ex. 807f); Ex. 20 (Trial Ex. 807i); Ex. 21 (Trial Ex. 807n); Ex. 22 (Trial Ex. 807p); Ex. 23 (Trial Ex. 807q); Ex. 24 (Trial Ex. 878a); *see also* Tr. 435:3-11, 436:11-13, 437:20-24, 438:7-10, 439:2-7, 439:20-22, 441:19-23, 443:4-6, 443:19-22 (discussing AbbVie's adverse event files listing MI and stroke as "unlabeled" events, confirming failure to warn). Dr. Pence testified that the cardiovascular risks should have been included in AndroGel's label by 2007. Tr. 2411:6-11.

AbbVie's criticisms of Dr. Ardehali's causation and adverse event analysis do no more than impermissibly challenge the weight of his testimony. AbbVie Mot. at 5-6. With respect to Dr. Pence, AbbVie resorts to distortions of her testimony. Dr. Pence's did not testify that the AndroGel label contained warnings about heart attacks in 2010. In fact, she stated the reverse was true. Tr. 2443:24-2444:2.

AbbVie's reliance on FDA review is similarly misplaced. AbbVie Mot. at 5. Any approvals of AndroGel labeling or advertisements were only relevant to the extent AndroGel was marketed to men suffering the conditions listed in the indications of use section of the AndroGel label. *See, e.g.*, Tr. 760:15-21; Ex. 25 (Trial Ex. 3223.5). More generally, AbbVie utterly misperceives the proper inquiry. The issue is one of AbbVie's knowledge and actions, and its choice to suppress safety concerns while touting unproven benefit.

Finally, Plaintiff presented abundant evidence that AndroGel was unreasonably dangerous pursuant to the consumer expectation and prudent manufacturer tests, contrary to AbbVie's assertions. AbbVie Mot. at 4. The jury properly weighed Plaintiff's evidence and found in his favor. *See, e.g.*, *Jackson v. Gen. Motors Corp.*, 60 S.W.3d 800, 805-06 (Tenn. 2001) (holding consumer expectation test applies in all Tennessee product liability cases, and that "the jury is to employ its own sense of whether the product meets ordinary expectations as to its safety under the circumstances presented by the evidence.") (internal citation omitted).[3]

2. Plaintiff Presented Substantial Evidence That AbbVie's Inadequate Warning Proximately Caused His Heart Attack

At the same time that it denies AndroGel increased CV risks, AbbVie relies on the "independent knowledge doctrine" to suggest Mr. Konrad's prescribing doctor, Dr. Overby, knew of this risk. AbbVie Mot. at 6. However, while Dr. Overby monitored hematocrit, there were several biological mechanisms through which AndroGel increased CV risk that no monitoring would reveal (and about which AbbVie knew and failed to warn). Indeed, the 2010 AndroGel label contained no CV warning, and thus Dr. Overby did not warn Mr. Konrad of heart attack risk. *See* Ex. 26 (Overby Dep. 139:19-140:1). That, of course, changed in 2015, when the company was

[3] AbbVie's cases are distinguishable because the experts in those cases did not testify that the products were defective or unreasonably dangerous. Here, in contrast, Plaintiff provided ample evidence that AndroGel was unreasonably dangerous. *See, e.g.*, Tr. 2408:20-2409:20, 2411:6-11 (Dr. Pence testifying the label failed to state heart attacks and strokes had been reported, and that AbbVie should have warned about CV risks "certainly by 2007."); Tr. 709:18-21 (Dr. Kessler testifying that "the way our system works is that doctors and all of us patients can have confidence that the drug is both safe and effective for those indications, and that's why you want to make sure the clinical trials were done…."). Moreover, Plaintiff demonstrated that the AndroGel was unreasonably dangerous independent of expert testimony. *See, e.g., supra* Sec. B.1., and *infra* Secs. C, D, E.

forced to add a CV warning; Dr. Overby now provides such warnings. Ex. 26 (Overby Dep. 129:4-12; 138:4-9).

Despite AbbVie's contention that the duty to warn extended only to Dr. Overby, the Court recognized in CMO No. 47 that causation in Tennessee "ultimately rests with the patient's decision to take or reject the medication." CMO 47 at 41 (citing *Payne v. Novartis Pharms. Co.*, 767 F.3d 526, 531-32 (6th Cir. 2014)). In that regard, with AbbVie's suppression of risk information from Dr. Overby, Mr. Konrad was denied the opportunity to make an informed decision based on the risks of the drug. Overby Dep. Tr. 138:4-14. Quite pointedly, however, had Dr. Overby been given such information, and a proper warning in turn provided, Mr. Konrad would not have taken AndroGel nor suffered his heart attack.

3. Plaintiff Also Demonstrated that AbbVie Failed to Test

The jury also heard substantial evidence of AbbVie's failure to adequately test AndroGel for the population of patients to which it promoted the drug, which – as AbbVie naturally fails to acknowledge – was an independent basis for the jury's negligence verdict. For example, both Steven Wojtanowski and Michael Miller admitted AbbVie never conducted any tests to establish the safety and efficacy of AndroGel to treat age-related hypogonadism. Tr. 291:14-25; 333:14-19; 1044:7-11 (Miller testimony); 325:25-327:2; Ex. 10 (Trial Ex. 23.8); Ex. 15 (Trial Ex. 60.4); Ex. 27 (Trial Ex. 112.20); Ex. 12 (Trial Ex. 238.2). Lacking substantial evidence of benefit for symptom relief, and ignoring FDA recommendation, AbbVie failed to pursue further studies. Ex. 28 (Trial Ex. 27.5). AbbVie's statement that FDA in 2011 found "substantial evidence from an adequate and well-controlled pivotal study" again misstates the issue, AbbVie Mot. at 5 (citing Trial Ex. 3180.10); there, FDA was addressing use in the limited population for which the FDA had approved the drug—not the population and uses AbbVie chose to market and promote the drug for. Though AbbVie never ran a study to demonstrate safety or efficacy in the patients it promoted the drug for, even where it had opportunities to support tests for safety and efficacy for age-related hypogonadism, it bypassed the chance by limiting funding, and thus study, in middle-aged men and for cardiovascular endpoints. Tr. 1131:24-1132:3, 1133:23-1134:1, 1134:2-10; Ex.

29 (Trial Ex. 292.1); Ex. 30 (Trial Ex. 293.1-2). AbbVie had no interest or intention to conduct the necessary studies as seen time and time again in corporate documents. *See* Ex. 31 (Trial Ex. 944); Ex. 32 (Trial Ex. 69.3) ("We do not plan on doing studies and there is no plan to do so"). *See also* Tr. 423:4-8; Ex. 33 (Trial Ex.919.1.).

C. Plaintiff's Presented Substantial Evidence of AbbVie's Intentional Misrepresentations

1. Plaintiff Proved that AbbVie Made False Statements of Material Fact

AbbVie contends that neither Plaintiff's experts nor any other witness identified a false statement of material fact in AbbVie's ads. This is simply not true. Aside from taking Dr. Kessler's statement that the ads "imply" safety and efficacy out of context, AbbVie fails to address Plaintiff's other evidence of false statements.[4]

Plaintiff presented evidence demonstrating that AbbVie consistently promoted AndroGel for non-indicated uses and the symptoms of aging. *See*, *e.g.*, Tr. 945:17-19, 945:24-946:7, 289:9-11, 329:21-330:10; Exs. 34-37, 2 (Trial Exs. 5-8, 9). On the record evidence, the jury could reasonably have determined that AndroGel was not effective (nor safe) for the treatment of such symptoms and conditions. Tr. 341:15-343:3, 350:5-11, 753:1-10, 945:4-11; Ex. 10 (Trial Ex. 23.8); Ex. 11 (Trial Ex. 25.6); Ex. 12 (Trial Ex. 238.1).

Even though AbbVie was told to submit an application for FDA review if it wanted to add symptoms to the indication, it never did. Tr. 945:18-19; 289:9-11. Nor did AbbVie ever study these symptoms. Tr. 946:1-7. Yet the company continued to market AndroGel as if it had. Mr. Wojtanowski admitted in his testimony that AbbVie promoted AndroGel for age-related hypogonadism and claimed significant symptom improvement over time in its marketing and advertising. Tr. 329:21-330:10, 466:14-467:16; Ex. 7 (Trial Ex. 154.5). For example, one advertisement falsely claimed that AndroGel had been proven safe over the course of a 42 month

[4] Because Plaintiff presented substantial evidence of false and misleading statements made by AbbVie and relied upon by Dr. Overby and Mr. Konrad, the cases AbbVie cites for the proposition that an implication is not a false representation are immaterial. Nonetheless, this Court previously determined that Dr. Kessler's testimony about the implications found within AbbVie's disease state awareness communications were not dispositive in favor of the Plaintiff but merely went to the weight of the evidence in support of Dr. Kessler's opinion. Tr. 792:3-5, 792:10-13.

study, *see* Ex. 7 (Trial Ex. 154.8), but AbbVie had not even conducted a controlled study to evaluate the long term safety of AndroGel. Tr. 332:23-25, 333:14-19. Similarly, the Shadows ad, which influenced Mr. Konrad to seek treatment, promised that testosterone could treat "low T" or symptoms such as low energy, low libido, and mood. *See* Ex. 5 (Trial Ex. 630). This too was incorrect because AbbVie had never established the efficacy of TRT for the treatment of these symptoms. *See, e.g.*, Tr. 341:15-343:3, 350:5-11; Ex. 10 (Trial Ex. 23.8); Ex.11 (Trial Ex. 25.6); Ex. 12 (Trial Ex. 238.1); Ex. 10 (Trial Ex. 23.8).[5] Through Michael Miller, the jury learned about the HIM study, a self-serving prevalence study funded by AbbVie published despite serious and substantial criticisms from the reviewers of the Journal of Clinical Endocrinology and Metabolism and multiple rejections only to be featured routinely in marketing materials. Tr. 1135:12-1154:7; Ex. 55 (Trial Ex. 950.10) (detailing AbbVie funding for HIM study); Ex. 56 (Trial Ex. 927.4) (reviewer calling the HIM study conclusions misleading); Ex. 57 (Trial Ex. 1025); Ex. 7 (Trial Ex. 154.1) ("13.8 million men may have low T, but 12.5 million go untreated"); Ex. 58 (Trial Ex. 448.5) ("Advertising/direct mail, detail piece highlighting low T prevalence with HIM data"). The Shadow Ad, viewed by millions, including Mr. Konrad, exhorted viewers "so don't blame it on aging," to persuade them to ask their doctors about Low T. Ex. 5 (Trial Ex. 630). Plaintiffs thus amply demonstrated that AbbVie made false and misleading statements regarding the safety and efficacy of AndroGel, with the intent to deceive patients and doctors. *See also* Ex. 6 (Trial Ex. 81) (proven safe); Ex. 8 (Trial Ex. 2000.5) (promising symptom improvement); Ex. 9 (Trial 585.7) (same).

Ignoring this evidence, AbbVie seizes on Dr. Kessler's use of the words "imply" and "implies" in an attempt to undermine Plaintiff's claim. AbbVie Mot. at 8. AbbVie conveniently

[5] The use of the term "Low T" in ads reviewed by FDA did not establish FDA's wholesale approval of any ad with that term, as AbbVie contends. Dr. Kessler explained that use of the term "Low T" would only be appropriate if it was consistent with the indication or if it was supported by substantial evidence of adequate and well-controlled clinical trials. Tr. 808:25-809:24. Dr. Kessler further testified that use of this term in ads referencing age-related hypogonadism, such as the Shadows ad, misrepresented AndroGel's indications. Tr. 805:20-806:2; 816:9-817:4. Moreover, FDA stated that despite receiving complaints about unbranded ads, such ads were not regulated by FDA. Tr. 970:3-12.

glosses over Dr. Kessler's testimony that "it would be false or misleading to market and promote AndroGel for these non-approved indications." Tr. 766:8-9. Dr. Kessler's explanation ("because it would imply that safety and efficacy were established") is immaterial to the broader point that AbbVie's marketing and promotion was unsubstantiated because "safety and efficacy was not established for these indications." Tr. 766:10-11. Moreover, as noted, beyond to Dr. Kessler's testimony, Plaintiff presented ample evidence of AbbVie false statements. *See* Exs. 6-9.

AbbVie argues that because the FDA reviewed AbbVie's branded ads, which touted symptom benefits that also appeared in the Shadow ad (an unbranded ad), AbbVie's ads cannot be misleading. AbbVie Mot. at 8. This argument has even less to commend to it. First, AbbVie fails to identify any evidence that demonstrates that FDA conducted a comprehensive review of AbbVie's branded ads. On the contrary, the evidence demonstrated that FDA's marketing review division was severely understaffed for many years and received substantially more ads than the division could review. Tr. 665:5-666:20; Ex. 38 (Trial Ex. 1427.23). Moreover, AbbVie does not dispute that FDA never reviewed its unbranded ads. Indeed, FDA publicly stated that it received complaints about unbranded ads but does not regulate such ads. Tr. 970:3-12. Second, Plaintiff presented evidence demonstrating that AbbVie's ads promoting uses of AndroGel for which proper testing had not been conducted—and thus for which substantial evidence was lacking—were unfounded. Tr. 753:7-21. Finally, AbbVie claim's that Dr. Kessler did not find the Shadow ad to be false and misleading is also incorrect. Dr. Kessler testified that the Shadow ad omitted the approved indication and made unsubstantiated treatment claims. Tr. 784:6- 785:1, 816:9-817:4.

2. Plaintiff Presented Substantial Evidence of Reliance on AbbVie's Misrepresentations

After seeing the Shadows ad, Mr. Konrad made an appointment with Dr. Overby to seek treatment for his symptoms: lower energy, weight gain, and libido. Tr. 1586:21-1587:1. Mr. Konrad asked his doctor if testosterone treatment could be beneficial for him. Tr. 1587:20-1588:1; *see also* Ex. 26 (Overby Dep. 172:5-7). When asked about his treatment of Mr. Konrad, Dr. Overby explained he was treating Mr. Konrad's symptoms of fatigue. Ex. 26 (Overby Dep. 172:20-173:5).

While fatigue was not part of the approved labeling, it was a symptom AbbVie targeted. Ex. 7 (Trial Ex. 154). Jennie Fields, AbbVie's sales representative assigned to Dr. Overby, admitted she used materials that suggested fatigue was a condition for which AndroGel could offer some benefit. Ex. 39 (Fields Dep. 95:25-96:19, 98:12-16). The result of AbbVie's concerted efforts was that Dr. Overby prescribed AndroGel to treat symptoms for which it had never been approved. AbbVie's arguments regarding Mr. Konrad's lack of reliance thus fail.

AbbVie similarly claims that the Dr. Overby was not swayed by AbbVie's marketing efforts. Plaintiff, however, offered extensive evidence showing how AbbVie targeted Dr. Overby with its marketing crusade. For example, the sales representative call notes for Dr. Overby illustrate the massive volume of sales visits to Dr. Overby, as well as the various marketing materials, such as discount cards and patient brochures, used by the reps to promote AndroGel. Ex. 26 (Overby Dep. 117:19-22, 118:21-119:3); Ex. 40 (Trial Ex. 2058); Ex. 41 (Trial Ex. 811). Dr. Overby confirmed he was detailed by AndroGel sales reps at least every two months. Ex. 26 (Overby Dep. 117:10-11). He also acknowledged receiving questionnaires and diagnostic devices to help him identify patients who would be good candidates for the AndroGel. Ex. 26 (Overby Dep. 122:18-23). Dr. Overby's overwhelming exposure to AbbVie's marketing messages (through serial sales visits and sales tools), coupled with his specific actions taken with Mr. Konrad—prescribing AndroGel for a presenting symptom of aging and to treat his "low t"—provide sound evidentiary underpinnings for the jury's determination of reliance.

D. Plaintiff Presented Substantial Evidence of Concealment and Intent to Deceive

AbbVie's focus on concealment from FDA is misplaced. Plaintiff demonstrated that AbbVie deliberately withheld from *doctors* and *patients* information regarding the safety and efficacy of AndroGel. AbbVie failed to warn doctors and patients that the safety and efficacy had not been established for age-related hypogonadism. Tr. 362:5-8, 324:24-325:2, 332:15-22, 333:14-19, 334:11-17. As Dr. Kessler noted, the Shadows ad seen by Mr. Konrad lacked risk information. Tr. 815:7-20. AbbVie's goal was to create a commercial highlighting efficacy while concealing

risk, which, as Mr. Wojtanowski confirmed, is exactly what AbbVie did. *See* Tr. 394:16-396:25; Ex. 31 (Trial Ex. 944.1). AbbVie deliberately withheld critical safety information from doctors and patients until 2015, when FDA mandated a label change to include a specific notice that AndroGel had not been established as safe and effective for age-related hypogonadism. Tr. 290:21-24. Any question about AbbVie's intent to deceive was for the jury to determine based on circumstantial evidence, so AbbVie's argument that Dr. Kessler did not testify to intent is inapt. *See, e.g.*, CMO 76 at 22 (Court limiting Plaintiff's expert's opinion on intent).

E. Plaintiff's Evidence Proves Culpability for Punitive Damages

Plaintiff established the necessary culpability for punitive damages under Illinois law because he demonstrated through substantial evidence that AbbVie's conduct, at a minimum, was willful and wanton, and, as set forth below in Section III *infra*, the amount of the punitive damages award comports with Due Process and Illinois law. As the jury instructions stated, "[t]he term 'willful and wanton' conduct means a course of action that shows actual or deliberate intention to harm or that, if not intentional, shows an utter indifference to or conscious disregard for the safety of others." Corrected Jury Instructions at 22 (*Konrad* Dkt. No. 109). Despite AbbVie's contentions to the contrary, Plaintiff established that AbbVie acted with flagrant indifference or conscious disregard to the public safety. *See* Section III, *infra*.

II. THE COURT SHOULD DENY ABBVIE'S MOTION FOR A NEW TRIAL

A. The Verdict Was Not Inconsistent

The jury found for Plaintiff on all claims except for strict liability. This, AbbVie argues, compels a new trial. AbbVie's challenge disregards the fundamental premise that district courts are required to interpret jury verdicts to avoid inconsistency. *See Deloughery*, 422 F.3d at 617; *Jamsports*, 382 F. Supp. 2d at 1060. Indeed, if there is "[a]ny plausible explanation for the verdict," a new trial must be denied. *Fox v. Hayes*, 600 F.3d 819, 844 (7th Cir. 2010)). By asserting that the verdict is inconsistent, AbbVie "is not entitled to a new trial unless no rational jury could have brought back the verdicts that were returned." *Deloughery*, 422 F.3d at 617 (citations omitted). In this case, there is no inconsistency, as there is clearly a plausible reconciliation of the verdict.

In addition to strict liability, the jury was instructed on claims for negligence, intentional misrepresentation, and misrepresentation by concealment. AbbVie narrowly focuses on strict liability and negligence because they both include similar elements addressing "unreasonably dangerous" and "causation." AbbVie self-servingly concludes that because it never disputed the first and third elements of the strict liability claim, the jury "necessarily found" that the second and fourth elements were the lynchpin elements that Plaintiff failed to prove because these same terms appear in Plaintiff's second claim for negligence for which the jury ruled in Plaintiff's favor. AbbVie Mot. at 15.

In addition to the deferential standard of review of a jury verdict, which affords every reasonable inference to Plaintiff as the non-moving party, AbbVie overlooks the fundamental difference in the jury charge for negligence, which focuses on AbbVie's conduct, with that for strict liability, which simply focuses on the product—AndroGel. Unlike the strict liability claim, where causation was focused on AndroGel's association with Mr. Konrad's heart attack, causation in the negligence claim focused on the association between AbbVie's actions (and inactions) in the face of particular duties and Mr. Konrad's injury. Further differentiating the negligence claim from that of the strict liability claim, the Court instructed the jury that:

> The manufacturer or seller of a product has a duty to use reasonable care in testing the product so that the product may be used safely in the manner and for the purpose for which it was sold. The failure to fulfill that duty is negligence.

This focus on testing and safe use of the product for the purpose for which it was sold differs remarkably from the strict liability claim's causal connection between AndroGel's unreasonably dangerous quality and Mr. Konrad's heart attack. It is entirely plausible that the jury determined that AndroGel was unreasonably dangerous, but found the necessary causal connection on Mr. Konrad's negligence claim satisfied upon consideration of the relationship between AbbVie's conduct in failing to reasonably test AndroGel for the purpose for which it was promoted and used by Mr. Konrad, and his injury—conduct-related considerations not relevant to the strict liability claim. Unsurprisingly, in similar instances, courts have been able to reconcile jury verdicts

finding negligent conduct but not strict liability. *See, e.g., Connelly v. Hyundai Motor Co.*, 351 F.3d 535, 542 (1st Cir. 2003) (finding "no reason to reverse the judgment because the jury returned opposite verdicts on the strict liability and negligence counts.")[6]

But even if AbbVie's argument regarding inconsistency with respect to the "unreasonably dangerous" element was well-founded, AbbVie ignores the jury's further verdicts on intentional misrepresentation and misrepresentation by concealment. These fraud claims contain no such element, and thus support no argument for inconsistency. Thus, even if there was something inconsistent about the jury's negligence verdict in contrast to its strict liability verdict (there is not), the Court in such circumstances may simply "excise[] the offending verdict while enforcing the remainder." *American Cas. Co. of Reading, Pa. v. B. Cianciolo, Inc.*, 987 F.2d 1302, 1305 (7th Cir. 1993).[7]

B. AbbVie's Challenges to the Jury Instructions are Untimely and Meritless

The jury instructions in this case, "as a whole," informed the jury of the applicable law "reasonably well," and did not mislead the jury in any sense. *Wilson v. Williams*, 83 F.3d 870, 874 (7th Cir. 1996). Reviewing courts will only reverse when "the jury was misled… to the prejudice of the complaining party." *Id.* (citations omitted). That did not occur here.

---

[6] *See also Talkington v. Atria Reclamelucifers Fabrieken BV*, 152 F.3d 254, 264 (4th Cir. 1998) (rejecting defendant's argument that finding of negligence was inconsistent with finding of no strict liability); *Sterner v. U.S. Plywood-Champion Paper, Inc.*, 519 F.2d 1352, 1354 (8th Cir. 1975) (same); *In re Vioxx Products Liability Litigation*, 523 F. Supp. 2d 471, 474 (E.D. La. 2007) (same); *Ramirez v. E.I. DuPont de Nemours & Co.*, 579 Fed. Appx. 878, 884 (11th Cir. 2014) (same); *State Farm Mut. Auto. Ins. Co. v. W.R. Grace & Co.*, 834 F. Supp. 1052, 1061 (C.D. Ill. 1993) (same); *Densberger v. United Technologies Corp.*, 125 F. Supp. 2d 585, 599 (D. Conn. 2000) (same); *Grant v. Westinghouse Elec. Corp.*, 877 F. Supp. 806, 810 (E.D.N.Y. 1995) (same); *Randall v. Warnaco, Inc., Hirsh–Weis Div.*, 677 F.2d 1226, 1231-32 & n.5 (8th Cir. 1982) (same) *see also Trull v. Volkswagen of America, Inc.*, 320 F.3d 1, 4 (1st Cir. 2002) (finding waiver of defendant, VW's, right to argue that verdicts were inconsistent and expressing "serious doubts" regarding defendant's argument that the verdicts were inconsistent, that the negligence finding of liability was nullified by the jury finding that VW was not liable on the claim of strict liability).

[7] As the *Cianciolo* court noted, "[a] judge may dissipate the inconsistency by setting aside one of the conflicting verdicts, if that verdict was unsupported by the evidence…. Yet the court, having found an irrational part of the verdict, does not annul the rest on the ground that the jury has displayed ecumenical inability or unwillingness to follow its instructions. Instead the court excises the offending verdict while enforcing the remainder." *Id.*

1. The Court's Instruction on Causation was Correct

AbbVie contends it was error to instruct the jury that AndroGel need not be the sole cause of Mr. Konrad's injury in the absence of multiple tortfeasors. This argument fails under Tennessee law. The substantial factor test applies to all torts under Tennessee law, as confirmed by AbbVie's own cited cases. *See, e.g.,* AbbVie Mot. at 17 (citing *inter alia Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863, 868-71 (W.D. Tenn. 2006). *Richardson*, a case with just one tortfeasor, demonstrates that a defendant's conduct need not be the sole cause of a plaintiff's injury under the "substantial factor" test. The court, in applying Tennessee's substantial factor test, stated, "[w]hile Plaintiff need not establish that Paxil was the sole or even last cause of his injuries, he must demonstrate that it was a 'substantial' or 'predominate' factor in the causation of his alleged injuries." *Id.* at 871. Further, AbbVie's reliance on Illinois law is inapposite, as Illinois law does not apply to this issue. *See* AbbVie Mot. at 17 (citing *Heitz v. Hogan*, 480 N.E.2d 185 (Ill. App. Ct. 1985)). The instructions regarding both cause in fact and legal cause are correct under Tennessee law. *See also* Letter from Plaintiff to the Court (Sept. 15, 2017) (*Konrad* Dkt. No. 75) (attached as Ex. 42) (regarding preliminary jury instructions); Letter from Plaintiff to the Court (Sept. 29, 2017) (*Konrad* Dkt. No. 105) (attached as Ex. 43) (regarding supplemental legal authority). AbbVie has not added anything to its previously asserted arguments on this point, and has failed to explain why the Court's causation instruction was purportedly in error.

2. The Court's Instruction on the Role of the FDA was Correct

(a) *AbbVie was always responsible for the content of its label.*

AbbVie first finds fault with the jury instruction regarding the role of the FDA because it did not include certain additional language requested by AbbVie. ("[I]f a manufacturer changes a warning without prior FDA approval, the 'FDA still must ultimately approve the [] change.'"). AbbVie Mot. at 17. AbbVie's argument is based on a hypothetical situation unsupported by the evidence, and thus fails. In reality, AbbVie did not change (nor proposed a change) to its label until FDA compelled it to do so in 2015, and this failure to act was a consideration for the jury in assessing AbbVie's liability. As previously recognized by the Court, a manufacturer may "add or strengthen a contraindication, warning, precaution, or adverse reaction" without waiting for FDA

approval. *See* CMO No. 47 at 16 (citing *Wyeth v. Levine*, 555 U.S. 555, 571, 572 (2009)). That is still true. The Court was nonetheless clear and accurate when it instructed the jury that a manufacturer does not need to "obtain[] ***prior*** FDA approval" before it strengthens its warnings. *See* Corrected Jury Instructions at 19 (emphasis added). In any event, having never proposed a warning of the serious CV risk with AndroGel use prior to 2010, AbbVie can point to no evidence that FDA would have refused such a warning to its AndroGel label.

(b) *The Court properly omitted any reference to "fraud on the FDA."*

AbbVie injects the issue of "fraud on the FDA" into its post-trial briefing without any justification. The instructions as given made it perfectly clear that Plaintiff was not asserting a claim for fraud on the FDA. *See* CMO No. 48 at 13-16; *see, e.g., Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 880-81 (N.D. Cal. 2013) ("*Buckman* does not mean plaintiffs cannot bring state law claims based on conduct that violates the FDCA."). Thus, there was no potential confusion, and it was clear that the fraud claims in this case required the jury to find that AbbVie defrauded Mr. Konrad and/or his physician in order to prevail. *See In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2017 WL 1836435, at *11 (N.D. Ill. May 8, 2017) (noting Plaintiff's claims do not rely on allegations that AbbVie defrauded FDA).

3. The Court Correctly Instructed the Jury on Punitive Damages

AbbVie rehashes its pretrial argument that the law of Plaintiff's home state should apply to the issue of punitive damages. The Court already explained its rationale for applying the law of AbbVie's home state to this issue, which remains correct. CMO No. 47 at 50-52; *see also Smith v. I-Flow Corp.*, 753 F. Supp. 2d 744, 749 (N.D. Ill. 2010).

C. AbbVie's Challenges to the Court's Evidentiary Rulings are Not Timely and are Without Merit

1. Testimony That AndroGel Advertising Was "Off-Label" Was Properly Admitted

The Court has already recognized that "Plaintiffs… have not asserted claims for off-label marketing of AndroGel…." CMO No. 48 at 12. Indeed, while evidence of AbbVie's statements and claims regarding AndroGel's use for unapproved conditions and symptoms is relevant to

Plaintiff's state law claims, Plaintiff brought no claim for violation of FDA regulations.[8] Accordingly, the jury was not misled and AbbVie's illusory argument is meritless. Moreover, AbbVie's reliance on *Buckman* is misplaced for the reasons the outlined in CMO 48 at 14-15.

2. Testimony Regarding AndroGel Sales and Profits Was Properly Admitted

As the Court previously ruled, "[u]nder Illinois law, 'evidence of net worth is… the preferred method of assessing punitive damages.'" *See* CMO No. 49 at 1-2 (internal citation omitted). Plaintiffs could thus properly introduce evidence of AbbVie's net worth for the purposes of punitive damages, which is exactly what Plaintiffs did. AbbVie did not object at trial to evidence of its net worth, which was stipulated. In fact, evidence of its net worth was introduced by stipulation. Tr. 1935:8-18. Thus, AbbVie's argument as to evidence of net worth is untimely and otherwise off the mark. Aside from net worth evidence, Plaintiff did not introduce evidence of AbbVie's "profit" during trial. With respect to evidence of sales, this evidence was directly relevant to Plaintiff's fraud claims, as well as for punitive damages, because it was relevant to show intent and motive. It likewise demonstrated the pervasive promotion and use of AndroGel well beyond patients with the labeled conditions and indications for use. The Court thus properly overruled AbbVie's objection on this point. Tr. 134:9-21.

3. Evidence of FDA Resources and its Inability to Meaningfully Review AndroGel Advertising and Other Submissions Was Properly Admitted

Evidence regarding the lack of FDA resources was relevant to rebut AbbVie's defenses, and excluding it would have prejudiced Plaintiff. AbbVie cannot use the FDA as a shield throughout trial, and then ask the Court to hide from the jury the fact that FDA lacked resources to actually accomplish what AbbVie consistently argued it should have accomplished. *See, e.g.*, Tr. 215:25-216:9 (AbbVie arguing "FDA was all over this product, from soup to nuts…"); Tr. 254:24-25, 672:4-16. Plaintiff foresaw this very argument that AbbVie now makes in responding to AbbVie's motion *in limine* on this issue:

[8] AbbVie acknowledged in closing arguments that Plaintiff did not assert this case involved violations of FDA regulations. *See, e.g.,* Tr. 3152:15-18 ("Counsel pointed out from the instructions you're not here to decide whether there was a violation of FDA rules. True enough." Tr. 3159:13-14 ("As Mr. Buchanan said a little while ago, the FDA is not on the verdict form.").

> Plaintiffs do not concede that evidence of FDA's insufficient resources and inability to effectively enforce its own rules should be excluded. Instead, Plaintiffs preserve their right to make a proffer for the evidence at trial (including the IOM report), especially to address any argument or evidence by AbbVie relating to FDA actions and inactions – in particular, argument or evidence ***attempting to shift responsibility for the content of AndroGel's post-approval label to FDA, or reliance on inaction by FDA as evidence of approval of AbbVie's conduct.***

Plaintiff's Response to AbbVie's MIL at 20-21 (emphasis added).

At trial, AbbVie did not object to the admission of evidence that described FDA's lack of resources. For example, Plaintiffs introduced into evidence a United States Government Accountability Office (GAO) report to Congress in November 2006, with "no objection" from the defense. Tr. 663:20-25; Ex. 38 (Trial Ex. 1427). This exhibit detailed FDA's substantial lack of resources, specifically in the area of direct-to-consumer marketing. Tr. 664:14-666:20*; see also* Tr. 2241:25-2247:14. Furthermore, at a sidebar early in the trial, the Court asked defense counsel point blank whether there was "a legitimate objection to the admissibility of [the 2007 Institute of Medicine (IOM) report, Exhibit 1339]" to which counsel responded, "no." Tr. 659:17-661:7.[9] Accordingly, AbbVie's post-trial argument fails.

4. Dr. Kessler's Testimony Was Properly Admitted[10]

The Court ruled at trial that AbbVie's objection to Dr. Kessler's testimony was untimely, and thus waived. Tr. 852:2-8.[11] In its motion, AbbVie merely re-urges its objection, while failing to address waiver. AbbVie Mot. at 21-22. This argument fails again. As the Court correctly determined, "[E]ven … when the objection on non-disclosure was made expressly, it wasn't supported." Tr. 851:19-21. The Court also correctly overruled an objection based on the "fit" requirement in *Daubert* and its progeny, finding AbbVie's argument goes to weight, not

[9] Even though AbbVie objected on the exhibit list under Rules 401, 403, and 802, their objections were waived as a result of counsel's admission at sidebar that there was no legitimate objection to the exhibit.

[10] AbbVie contends in a footnote (AbbVie Mot. at 6 n.10) that the testimony of Drs. Ardehali and Pence should not have been admitted. However, Plaintiffs do not concede that AbbVie properly preserved for appeal "all of its objections to Plaintiff's expert testimony." *Id.*

[11] AbbVie failed to object to this testimony in a timely manner despite the fact that Dr. Kessler had given similar testimony at his deposition, at the original *Konrad* trial, and in the *Mitchell* bellwether trial. *Konrad I* Tr. 546:7-8, 549: 5-14 (excerpts attached hereto as Ex. 44); *Mitchell* Tr. 859:11-16 (excerpts attached hereto as Ex. 45); Kessler Dep. Jan. 12, 2017, 141:14-25, 267:11-19 (excerpts attached hereto as Ex. 46).

admissibility. Tr. 852:9-20; Minute Entry Sept. 21, 2017 (*Konrad* Dkt. No. 90). AbbVie fails to explain why the Court's prior determinations were in error, let alone manifest error.

D. The Verdict Is Not Against the Weight of the Evidence

In passing, AbbVie offers the conclusory argument that a new trial is necessary because the verdict was against the weight of the evidence. AbbVie Mot. at 22. But AbbVie does not develop that point in any meaningful way, offering no substantive argument and merely re-citing the evidence discussed elsewhere in its Motion. Plaintiff's claims were all supported by substantial evidence, and there was no manifest error. Accordingly, a new trial is not warranted.

III. THE COURT SHOULD DENY ABBVIE'S MOTION FOR REMITTITUR OF THE PUNITIVE DAMAGES AWARD

AbbVie contends that the punitive damages award does not comport with Due Process or Illinois law (AbbVie does not contest the amount of compensatory damages). AbbVie's request for remittitur should be denied.

The Supreme Court's decision in *State Farm v. Campbell***,** 538 U.S. 408, 416 (2003), prohibited only "grossly excessive" or "arbitrary" punishments. 538 U.S. at 419. Merely contending that its conduct was not reprehensible, AbbVie fails to address Plaintiff's evidence demonstrating the constitutionality of the punitive damages award, which, in this case comported with the following guideposts established by the Supreme Court: (1) the degree of reprehensibility of the defendant's conduct; (2) the disparity between the harm or potential harm suffered by the plaintiff and his punitive damages award; and (3) the differences between the punitive damages award and the civil penalties authorized or imposed in comparable cases. *Campbell*, 538 U.S. at 419; *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 574-75 (1996). The reprehensibility factor is the one that courts primarily look to in deciding the reasonableness of the jury's award. *Gore*, 517 U.S. at 575. The "reprehensibility" guidepost has five factors of its own, namely whether: (1) "the harm caused was physical as opposed to economic"; (2) the defendant's "conduct evinced an indifference to or a reckless disregard of the health or safety of others"; (3) "the target of the conduct had financial vulnerability"; (4) "the conduct involved repeated actions or was an isolated incident"; and (5) "the harm was the result of intentional malice, trickery, or deceit, or

mere accident." *Campbell*, 538 U.S. at 419 (citing *Gore* at 576-77). While AbbVie contends its conduct was not reprehensible, the five reprehensibility considerations weigh heavily in favor of maintaining the jury's punitive damages award. AbbVie Mot. at 23.

First, it is undisputed that Mr. Konrad suffered a life threatening injury and endured significant pain and suffering, which further put him at an increased risk of, *inter alia*, sudden death and heart failure. Tr. 1597:7-1598:7; 1667:7-17, 1739:21-1740:18-23. Second, AbbVie's conduct exhibited reckless disregard and indifference to millions of middle-aged men who were exposed to AbbVie's misrepresentations over the course of its deceptive marketing crusade. *See Philip Morris USA v. Williams*, 549 U.S. 346, 357 (2007) (finding jury may take into account conduct risking harm to many is more reprehensible than conduct risking harm to only a few). The jury heard evidence from AbbVie's own employees that the company had never established the safety and efficacy of AndroGel for treatment of age-related hypogonadism. Tr. 291:2-25. Mr. Wojtanowski admitted that any patient using AndroGel for age-related hypogonadism was using a drug that had not been proven safe or effective for that condition. Tr. 290:25-291:25. AbbVie also failed to perform testing to establish the long-term safety of AndroGel, particularly CV safety, Tr. 333:14-19, 1044:7-11; Ex. 33 (Trial Ex. 919), and fought efforts to update the label to reflect AndroGel's unknown safety and efficacy profile hiring professionals to combat the class labeling effort. Ex. 47 (Trial Ex. 925); Tr. 367:10-21, 368:11-17, 369:12-14, 374:16-21. AbbVie's failure to meet its obligations to adequately test AndroGel is compounded by its awareness of the potential for CV events. As Dr. Scarazzini agreed, "risk is risk," and AbbVie ignored the numerous biologically plausible risks posed by testosterone. Tr. 2337:2-3, 1065:7-11; Ex. 27 (Trial Ex.112.22-23); Ex. 48 (Trial Ex. 28.8).

Third, AbbVie's net worth is a factor to consider, and a suitably large award is necessary to punish and deter a company of AbbVie's size from targeting those, like Mr. Konrad, who are vulnerable. *See Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22 (1991). In this case, the stipulated net worth of AbbVie at the end of 2016 was $5.6 billion. Tr. 1935:17-18. Thus, the jury's award of compensatory and punitive damages was approximately 2.5% of AbbVie's net

worth and well within reason. *See, e.g., Blount v. Stroud*, 915 N.E.2d 925, 940-41 (Ill. App. 2009) (affirming an award that was approximately 3% of defendant's net worth); *O'Neill v. Gallant Insurance Co.*, 769 N.E.2d 100 (Ill. 2002) (upholding punitive damage award that was 10% of the defendant's net worth); *Howard v. Zack Co.*, 637 N.E.2d 1183, 1194 (Ill. App. 1994) (upholding punitive damage award that was 5% of defendant's net worth). As noted by the court in *Blount*:

> Juries have the unique ability to articulate community values and evaluate the reprehensibility of a defendant's conduct for the purposes of awarding punitive damages. The jury could have found the nature of [Defendant's] conduct to be egregious, and when factored against his substantial wealth, it could have determined that [Defendant's] conduct warranted $2.8 million dollars in punitive damages. This amount represents roughly 3% of Stroud's net worth, and we cannot say that this sum was the result of passion or prejudice on the part of the jury.

Blount, 915 N.E.2d at 940 (citations and internal quotation marks omitted).

Fourth, as detailed elsewhere, AbbVie's fraud was not an isolated incident, but rather a pervasive, nationwide crusade to put every aging male in America on AndroGel. *See* Ex. 1 (Trial Ex. 1); Ex. 49 (Trial Ex. 2); Ex. 2 (Trial Ex. 9.33); Ex. 10 (Trial Ex. 23); Ex. 28 (Trial Ex. 27); Ex. 50 (Trial Ex. 115); Ex. 51 (Trial Ex. 39); Tr. 291:14-17, 348:4-15, 350:5-11, 323:11-324:4, 456:15-457:11, 382:13-21, 384:20-385:9.

Finally, AbbVie's fraudulent conduct reflects the serious, sometimes fatal CV risks of AndroGel. AbbVie callously put Mr. Konrad at risk for the sake of corporate profits. *See, e.g.,*; Tr. Tr. 391:14-396:22, 1025:5-1026:7, 1027:5-10; Ex. 5 (Trial Ex. 630); Ex. 31 (Trial Ex. 944); Ex. 52 (Trial Ex. 945). Punitive damages awards are necessary to punish and deter large, profitable companies that would view an unreasonably low award as a mere cost of doing business. *See Exxon Shipping Co. v. Baker*, 554 U.S. 471, 492-93 (2008) (recognizing twin goals of retribution and deterrence); *Kemp v. Am. Tel. & Tel. Co.*, 393 F.3d 1354, 1364 (11th Cir. 2004) ("sometimes a bigger award is needed to attract the … attention of a large corporation in order to promote deterrence effectively") (internal quotation marks omitted). *See also* Pl.'s Reply Br. in support of Mot. to Am. J. at 6, *Mitchell v. AbbVie, Inc.*, No. 1:14-cv-09178 (N.D. Ill. 2017) (MDL Dkt. No. 2268) (*Mitchell* Dkt. No. 110) (attached hereto as Ex. 53).

Holdings from state and federal courts across the country repeatedly have supported sizable punitive damage awards, irrespective of the size of the corresponding compensatory awards.[12] *See, e.g., TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993) (affirming $10 million punitive damages award with a $19,000 compensatory award (526:1)); *Kemp*, 393 F.3d at 1364 (11th Cir. 2004) (allowing punitive damages 2,172 times compensatory damages in fraud case); *In re Estate of Hoellen*, 367 Ill. App. 3d 240, 251-53 (2006) (jury awards of nominal damages ($1) and punitive damages ($50,000)); *Lewellen v. Franklin*, 441 S.W. 3d 136, 148 (Mo. 2014) (recognizing that single-digit ratios are not appropriate when egregious conduct results in a low compensatory damage award); *cf. In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2014 WL 5461859, at *55 (W.D. La. Oct. 27, 2014) (court employing 25:1 multiplier in reduction of punitive damage award).

CONCLUSION

Based on the foregoing, AbbVie's post-trial motion should be denied in its entirety.

Dated: December 1, 2017

Respectfully submitted,

/s/ David R. Buchanan

David R. Buchanan
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: dbuchanan@seegerweiss.com

Troy Rafferty
LEVIN PAPANTONIO THOMAS

[12] Indeed, an independent jury empaneled in a separate bellwether trial in this MDL, *Mitchell v. AbbVie Inc.*, Case No. 14-cv-09178 (N.D. Ill. 2017) (Kennelly, J.), returned a verdict finding for the plaintiff on his claims of intentional misrepresentation, and returned a punitive damages award of $150 million after hearing similar evidence of AbbVie's conduct concerning AndroGel. *See Mitchell* Judgment entered July 24, 2017 (*Mitchell* Dkt. No. 87) (attached hereto as Ex. 54). Illinois law governed the punitive damages award in both cases, and it is not a coincidence that AbbVie was punished to a similar degree by a second jury. As the Court is aware, the *Konrad* and *Mitchell* cases proceeded on coordinated pretrial schedules, with, for example, their final pretrial orders due on the same day and shared many of the same witnesses and exhibits, but were tried before separate juries starting in July 2017 (for *Mitchell*) and September 2017 (for *Konrad*, after the mistrial of the first *Konrad* trial that started in June 2017). If the Court amends the judgment in the *Mitchell* case to include the undisputed amount of medical expenses, the compensatory damages award and punitive damages award will be similar in both cases.

MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7163
trafferty@levinlaw.com

Bill Robins III
ROBINS CLOUD LLP
808 Wilshire, Suite 450
Santa Monica, California
Tel: (310) 929-4200
Fax: (310) 566-5900
Email: robins@robinscloud.com

Matthew P. Teague, Esq.
BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.
P.O. Box 4160
Montgomery, AL 36103-4160
Tel: (334) 269-2343
Fax: (334) 954-7555
Email: matt.teague@beasleyallen.com

Counsel for Plaintiffs Jeffrey Konrad and Jana Konrad

Trent B. Miracle
SIMMONS HANLY CONROY
One Court Street
Alton, IL 62002
Phone: (618) 259-2222
Fax: (618) 259-2252
Email: tmiracle@simmonsfirm.com

Ronald Johnson, Jr.
SCHACHTER, HENDY & JOHNSON PSC
909 Wrights Summit Parkway, Suite 210
Ft. Wright, KY 41011
Phone: (859) 578-4444
Fax: (859) 578-4440
Email: rjohnson@pschacter.com

Christopher A. Seeger
SEEGER WEISS LLP
77 Water Street
New York, NY 10005
Phone: (212) 584-0700
Fax: (212) 584-0799
Email: cseeger@seegerweiss.com

MDL Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/David R. Buchanan
David R. Buchanan